Horizon Pharma plc
Form 8-K
February 28, 2019

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d)

of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): February 28, 2019

Horizon Pharma Public Limited Company

(Exact name of registrant as specified in its charter)

Ireland	**001-35238**	**Not Applicable**
(State or other jurisdiction of incorporation)	**(Commission File No.)**	**(IRS Employer Identification No.)**

Connaught House, 1st Floor, 1 Burlington Road, Dublin 4, D04 C5Y6, Ireland

(Address of principal executive offices)

Registrant s telephone number, including area code: 011-353-1-772-2100

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934.

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01 Other Events.

On February 28, 2019, Horizon Pharma Public Limited Company (the Company) reported topline results from its Phase 3 confirmatory trial evaluating teprotumumab for the treatment of active thyroid eye disease (TED). The study met its primary endpoint, showing more patients treated with teprotumumab compared with placebo had a meaningful improvement in proptosis, or bulging of the eye: 82.9 percent of teprotumumab patients compared to 9.5 percent of placebo patients achieved the primary endpoint of a 2 mm or more reduction in proptosis ($p<0.001$). Proptosis is the main cause of morbidity in TED. All secondary endpoints were also met and the safety profile was consistent with the Phase 2 study of teprotumumab in TED.

Additional details from the Phase 3 confirmatory trial, titled OPTIC (Treatment of Graves **O**rbitopathy (Thyroid Eye Disease) to Reduce **P**roptosis with **T**eprotumumab **I**nfusions in a Randomized, Placebo-Controlled, **C**linical Study), include:

- Designed to investigate the efficacy, tolerability and safety of teprotumumab in patients with active TED.

- Eighty-three patients were assigned to receive teprotumumab or placebo in eight intravenous infusions (10mg/kg for their first infusion followed by 20mg/kg for the remaining seven infusions) every three weeks for 21 weeks.

- The primary endpoint was a responder rate of ³ 2 mm reduction of proptosis in the study eye (without deterioration in the fellow eye) at Week 24.

- In the intent-to-treat population, 34/41 (82.9%) patients receiving teprotumumab and 4/42 (9.5%) patients receiving placebo were proptosis responders at Week 24 ($p<0.001$).

- All secondary endpoints were also met, which include the effect of teprotumumab vs. placebo on:

  - Overall responder rate at Week 24 (primary endpoint in the Phase 2 study): Percent of participants with ³2 point reduction in Clinical Activity Score (CAS) and ³2 mm reduction in proptosis from baseline, provided there is no corresponding deterioration (³2-point/mm increase) in CAS or proptosis in the fellow eye.

  - Percent of participants with a CAS value of 0 or 1 at Week 24 in the study eye.

  - Percent of patients with a change from baseline of at least one grade in diplopia (double vision).

  - Mean change in proptosis measurement from baseline to Week 24 in the study eye.

Mean change in Graves Ophthalmopathy Quality of Life from baseline to Week 24.

The safety profile of teprotumumab in OPTIC was similar to that seen in the Phase 2 study with no new safety observations. The drop-out rate was low (<5%) and balanced across placebo and treatment arms. There were no deaths during the study and a total of 3 serious adverse events: in the placebo arm, one patient had a visual field defect and received orbital decompression surgery; in the teprotumumab arm, one patient had pneumothorax (considered not related to study drug) and another had an infusion reaction. The vast majority of treatment-emergent adverse events were mild to moderate in intensity and did not lead to discontinuation.

Item 1.01 Entry into a Material Definitive Agreement.

Rights Agreement

Item 3.03 below is incorporated herein by reference.

Item 3.03. Material Modification to Rights of Security Holders.

On February 28, 2019, the Company entered into a Rights Agreement (the Rights Agreement), with Computershare Trust Company, N.A., as rights agent. The Board of Directors of the Company (the Board) has authorized the issuance of one ordinary share purchase right (a Right) for each outstanding ordinary share, par value $0.0001 per share, of the Company (the ordinary shares). Each Right represents the right to purchase one-fifth of an ordinary share of the Company, upon the terms and subject to the conditions of the Rights Agreement. The Rights will be issued to the shareholders of record on March 11, 2019 and will expire on February 28, 2020.

The Board has adopted the Rights Agreement to enable all shareholders of the Company to realize the long-term value of their investment in the Company and to guard against attempts to acquire control of the Company at an inadequate price. In general terms, the Rights Agreement works by causing significant dilution to any person or group that acquires 10% (or 15% in the case of an existing 13G Investor as defined in the Rights Agreement) or more of the outstanding ordinary shares of the Company without the prior approval of the Board. The Rights Agreement is not intended to prevent an acquisition of the Company on terms that the Board considers favorable to, and in the best interests of, all shareholders. Rather, the Rights Agreement aims to provide the Board with adequate time to fully assess any takeover proposal and therefore comply with its fiduciary duties and to encourage anyone seeking to acquire the Company to negotiate with the Board prior to attempting a takeover. The Rights Agreement was adopted in response to the takeover environment in general, particularly in light of the Company s evolution into a biopharma company focused on rare diseases and rheumatology, the Phase 3 clinical trial results of its rare disease drug candidate teprotumumab announced on February 28, 2019 and the market opportunity for KRYSTEXXA and teprotumumab and is not in response to any specific approach to the Company or perceived imminent takeover proposal for the Company. The issuance of Rights is not taxable to the Company or to shareholders and will not affect reported earnings per share. A summary of the terms of the Rights Agreement follows.

The Rights. The Rights will initially trade with, and will be inseparable from, the ordinary shares. The Rights are evidenced only by certificates or book-entry credits that represent ordinary shares. New Rights will accompany any new ordinary shares the Company issues after the Record Date (as defined in the Rights Agreement) until the earlier of the Distribution Date described below and any redemption or expiration of the Rights.

Exercisability. The Rights will not be exercisable until 10 days after the public announcement that a person or group has become an Acquiring Person by obtaining beneficial ownership of 10% (or 15% in the case of a 13G Investor, as defined in the Rights Agreement) or more of the Company s outstanding ordinary shares.

The date when the Rights become exercisable is referred to as the Distribution Date. Until that date, the certificates or book-entry credits that represent ordinary shares will also evidence the Rights, and any transfer of ordinary shares will constitute a transfer of Rights. After that date, the Rights will separate from the ordinary shares and be evidenced by book-entry credits. Any Rights held by an Acquiring Person are null and void and may not be exercised.

Exercise Price. Each Right will allow its holder to purchase from the Company one-fifth of an ordinary share for $45.00 (the Exercise Price), once the Rights become exercisable. Prior to exercise, the Right does not give its holder any dividend, voting, or liquidation rights.

Beneficial Ownership. Certain synthetic interests in securities created by derivative positions, whether or not such interests are considered to be ownership of the underlying ordinary shares or are reportable for purposes of Regulation 13D of the Securities Exchange Act of 1934, as amended, are treated as beneficial ownership of the number of the Company s ordinary shares equivalent to the economic exposure created by the derivative position, to the extent actual ordinary shares of the Company are directly or indirectly held by counterparties to the derivatives contracts.

Shares held by Affiliates and Associates (each as defined in the Rights Agreement) of an Acquiring Person, and Notional Ordinary Shares (as defined in the Rights Agreement) held by counterparties to a Derivatives Contract (as defined in the Rights Agreement) with an Acquiring Person, will be deemed to be beneficially owned by the Acquiring Person.

Consequences of a Person or Group Becoming an Acquiring Person

Flip In. If a person or group becomes an Acquiring Person, all holders of Rights except the Acquiring Person may, upon exercise of the Rights, purchase for $45.00 ordinary shares of the Company with a value of $90.00 based on the then market price of the ordinary shares.

Reduction in Exercise Price. After a person or group becomes an Acquiring Person, but before an Acquiring Person owns 50% or more of the Company s outstanding ordinary shares, the Board may provide that each Rights holder, other than the Acquiring Person, will have the right to receive, upon exercise of a Right, one-fifth of an ordinary share for a purchase price of $0.50 per Right. If the Board makes such a determination, the

option of a Rights holder to so exercise Rights shall be in addition to, but not in duplication of, any rights of holders to exercise Rights as described in Flip In above.

Flip Over. If the Company is later acquired in a merger or similar transaction after the Distribution Date, all holders of Rights except the Acquiring Person may purchase shares of the acquiring company with a market value of $90.00 based on the market price of the acquiring company s stock, prior to such transaction.

Expiration. The Rights will expire on February 28, 2020.

Redemption. The Board may redeem the Rights without consideration therefor at any time before any person or group becomes an Acquiring Person. If the Board redeems any Rights, it must redeem all of the Rights.

Anti-Dilution Provisions. The Board may adjust the purchase price for one-fifth of an ordinary share, the number of ordinary shares issuable and the number of outstanding Rights to prevent dilution that may occur from a stock dividend, a stock split, or a reclassification of the ordinary shares. No adjustments to the Exercise Price of less than 1% will be made.

Amendments. The terms of the Rights Agreement may be amended by the Board without the consent of the holders of the Rights. After a person or group becomes an Acquiring Person, the Board may not amend the Rights Agreement in a way that adversely affects holders of the Rights.

The foregoing description of the Rights Agreement does not purport to be complete and is qualified in its entirety by reference to the complete text of the Rights Agreement, which has been filed as Exhibit 4.1 to this Current Report on Form 8-K. A copy of the Rights Agreement is available free of charge from the Company upon request.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	**Description**
4.1	Rights Agreement, dated as of February 28, 2019, between Horizon Pharma Public Limited Company and Computershare Trust Company, N.A.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements, including, but not limited to, statements related to the Rights Agreement and the Rights to be issued thereunder, and other statements that are not historical facts. These forward-looking statements are based on the Company s current expectations and inherently involve significant risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks and uncertainties related to: potential challenges to the Rights Agreement under applicable law and those other risks detailed from time to time under the caption Risk Factors and elsewhere in the Company s Securities and Exchange Commission filings and reports (Commission File No. 001-35238), including the Company s Annual Report on Form 10-K for the year ended December 31, 2017 and future filings and reports by the Company. The Company undertakes no duty or obligation to update any forward-looking statements contained in this Current Report on Form 8-K as a result of new information, future events or changes in its expectations.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: February 28, 2019

HORIZON PHARMA PUBLIC LIMITED COMPANY

By: /s/ Paul W. Hoelscher
Paul W. Hoelscher
Executive Vice President and Chief Financial Officer